### Frequently-Asked Questions About Influenza Vaccine

Content for most of these questions was adapted from the Immunization Action Coalition--IAC (<a href="www.immunize.org/askexperts/experts">www.immunize.org/askexperts/experts</a> inf.asp), Centers for Disease Control and Prevention--CDC (<a href="www.cdc.gov/flu/professionals/vaccination/index.htm">www.cdc.gov/flu/professionals/vaccination/index.htm</a>), and the California Immunization Program (<a href="www.eziz.org">www.eziz.org</a>) on 10/1/10. We thank the IAC, CDC, and the California Immunization Program for providing this information.

#### **General Information**

#### Who should get seasonal flu vaccine?

Beginning in 2010, the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices (ACIP) recommends that *everyone 6 months and older should get a flu vaccine each year*. This vote for "universal" flu vaccination in the U.S. expands protection against the flu to more people.

While flu vaccine benefits everyone, it's especially important that the following groups get vaccinated either because they are at high risk of having serious flu-related complications or because they live with or care for people at high risk for developing flu-related complications:

- Pregnant women
- Children younger than 5, but especially children younger than 2 years old
- People 50 years of age and older
- People of any age who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)
- People who are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus);
- Children aged 6 months--18 years and receiving long-term aspirin therapy and who therefore might be at risk for experiencing Reye syndrome after influenza virus infection
- People who are residents of nursing homes and other long-term care facilities
- American Indians/Alaska Natives
- People who are morbidly obese (body-mass index is 40 or greater)
- People who live with or care for those at high risk for complications from flu, including:
  - 1. Health care workers
  - 2. Household contacts of persons at high risk for complications from the flu
  - 3. Household contacts and out of home caregivers of children less than 6 months of age (these children are too young to be vaccinated)

Flu vaccine is already available now, but I've heard protection from seasonal influenza vaccine declines or wanes within 3 or 4 months of vaccination. Should I wait until October or November to vaccinate my elderly or medically frail patients?

Evidence from clinical trials suggests that protection against viruses that are similar antigenically to those contained in the vaccine extends for at least 6--8 months. Three years after vaccination with the A/Hong Kong/68 vaccine, vaccine effectiveness was 67% for prevention of influenza caused by the A/Hong Kong/68 virus. In randomized trials

conducted among healthy college students, immunization with TIV provided 92% and 100% efficacy against influenza H3N2 and H1N1 illnesses, respectively, during the first year, and a 68% reduction against H1N1 illness during the second year (when the predominant circulating virus was H1N1) without revaccination. In a similar study of young adults in 1986-1987, TIV reduced influenza A (H1N1) illness 75% in the first year, H3N2 illness 45% in the second year, and H1N1 illness 61% in the third year after immunization. Serum anti-influenza antibodies and nasal IgA elicited by vaccination remain detectable in children vaccinated with LAIV for more than 1 year. In one community-based nonrandomized open label trial, continued protection from medically attended acute respiratory illness during the 2000--01 influenza season was demonstrated in children who received only a single dose of LAIV during the 1999--2000 season.

Adults aged ≥65 years typically have a diminished immune response to influenza vaccination compared with young healthy adults, suggesting that immunity might be of shorter duration (although still extending through one influenza season). However, a review of the published literature concluded that no clear evidence existed that immunity declined more rapidly in the elderly, and additional vaccine doses during the same season do not increase the antibody response. One study that measured the proportion of persons who retained seroprotective levels of anti-influenza antibody declined in all age groups, including those aged ≥65 years, within 1 year of vaccination. However, the proportion in each age group that retained seroprotective antibody levels remained above standards typically used for vaccine licensure for seasonal influenza A (H1N1) and influenza A (H3N2) in all age groups. In this study, anti-influenza B antibody levels declined more guickly, but remained elevated well above licensure threshold for at least 6 months in all age groups. The frequency of breakthrough infections is not known to be higher among those who were vaccinated early in the season. Infections among the vaccinated elderly might be more likely related to an age-related reduction in ability to respond to vaccination rather than reduced duration of immunity.

#### How effective is the flu shot?

In studies of the seasonal flu shot, when the "match" between vaccine viruses and circulating viruses is close, the vaccine has been shown to prevent influenza in about 70%-90% of healthy persons younger than age 65 years. However, effectiveness among adults aged <65 years who are at higher risk for influenza complications typically is lower than that reported for healthy adults. Among elderly persons living outside chronic-care facilities (such as nursing homes) and those persons with long-term (chronic) medical conditions (such as asthma, diabetes, or heart disease), the flu shot has been shown to be between 30% and 70% effective in preventing hospitalization for pneumonia and influenza. Among elderly nursing home residents, the flu shot has been shown to be most effective in preventing severe illness, secondary complications, and deaths related to the flu. In this population, the shot has been shown to be between 50% and 60% effective in preventing hospitalization or pneumonia and 80% effective in preventing death from the flu.

#### How effective is the nasal-spray seasonal flu vaccine LAIV (FluMist®)?

In one large study among children aged 15-85 months, the seasonal nasal-spray flu vaccine LAIV (FluMist®) reduced the chance of influenza illness by 92% compared with placebo. In a study among adults, the participants were not specifically tested for influenza. However, the study found 19% fewer severe febrile respiratory tract illnesses, 24% fewer respiratory tract illnesses with fever, 23-27% fewer days of illness, 13-28% fewer lost work days, 15-41% fewer health care provider visits, and 43-47% less use of antibiotics compared with placebo. Other studies have found TIV to be superior to LAIV.

For more information about the efficacy of LAIV and TIV, go to www.cdc.gov/flu/professionals/vaccination/effectivenessga.htm

#### Is TIV or LAIV superior?

Both TIV and LAIV have been demonstrated to be effective in children and adults. However, data directly comparing the efficacy or effectiveness of these two types of influenza vaccines are limited and insufficient to identify whether one vaccine might offer a clear advantage over the other in certain settings or populations. For details about efficacy studies for TIV and LAIV, see <a href="https://www.cdc.gov/flu/professionals/vaccination/">www.cdc.gov/flu/professionals/vaccination/</a>.

#### What strains are in this year's flu vaccine?

The 2010--11 trivalent vaccines will protect against three strains of influenza expected to be circulating this season: A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The influenza A (H1N1) vaccine virus is derived from a 2009 pandemic influenza A (H1N1) virus.

### Some patients refuse influenza vaccination because they insist they "got the flu" after receiving the injectable vaccine in the past. What can I tell them?

There are several reasons why this misconception persists:

- 1. Less than 1% of people who are vaccinated with the injectable vaccine develop flu-like symptoms, such as mild fever and muscle aches, after vaccination. These side effects are not the same as having influenza, but people confuse the symptoms.
- 2. Protective immunity doesn't develop until 1-2 weeks after vaccination. Some people who get vaccinated later in the season (December or later) may get influenza shortly afterward. These late vaccinees develop influenza because they were exposed to someone with the virus before they became immune. It is not the result of the vaccination.
- To many people, "the flu" is any illness with fever and cold symptoms. If they get any
  viral illness, they may blame it on the flu shot or think they got "the flu" despite being
  vaccinated. Influenza vaccine only protects against certain influenza viruses, not all
  viruses.
- 4. The influenza vaccine is not 100% effective, especially in older persons.
- 5. Ocular or respiratory symptoms have been reported occasionally within 24 hours after TIV administration, but these symptoms typically are mild and resolve quickly without specific treatment.

#### What are the differences between all the formulations of flu vaccine?

The various influenza vaccine preparations have different age and dose indications and different recommended routes, as licensed by the FDA. Multiple-dose vials contain thimerosal as a preservative. Single-dose vials and prefilled syringes do not contain thimerosal or any other preservative. A table showing all U.S. flu vaccine formulations for the 2010-11 season is available at <a href="https://www.cdc.gov/flu/pdf/dosagechart.pdf">www.cdc.gov/flu/pdf/dosagechart.pdf</a>.

### How much influenza vaccine is projected to be available for the 2010-11 influenza season?

At the current time, six influenza vaccine manufacturers are projecting that as many as 160-165 million doses of influenza vaccine will be available from currently licensed manufacturers in the U.S. for use during the 2010-11 influenza season.

### How much thimerosal-free influenza vaccine is expected to be available for the 2010-11 season?

For the 2010-11 season, manufacturers project producing approximately 74 million doses of thimerosal-free or preservative-free (trace thimerosal) influenza vaccine.

#### Can I still buy influenza vaccine for the 2010-11 season?

Influenza vaccine pre-booking typically occurs between January and March, though most preparations of vaccine should still be available for purchase. Providers should contact distributors and local vendors about remaining supply. Information about distributors who still have influenza vaccine available for sale can be found at <a href="https://www.preventinfluenza.org/ivats/">www.preventinfluenza.org/ivats/</a>

#### Vaccination of Children

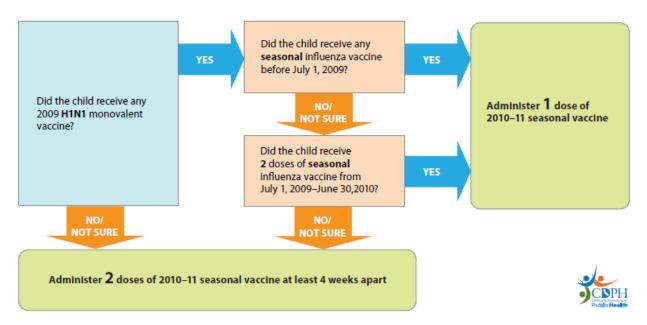
### How do I determine whether a child needs one or two doses of seasonal influenza vaccine for 2010-11?

California Immunization Program has developed a simple flow chart to help you decide how many doses a child needs. You can access the flow chart at <a href="https://www.eziz.org/PDF/IMM-1033B.pdf">www.eziz.org/PDF/IMM-1033B.pdf</a>

2010–11 SEASONAL INFLUENZA VACCINE

### 2 DOSES FOR MOST CHILDREN 6 MONTHS THROUGH 8 YEARS OF AGE

How many doses does your patient age 6 months through 8 years need?



Persons 9 years and older need  $oldsymbol{1}$  dose of 2010-2011 seasonal influenza vaccine

## We've heard that ACIP has limited the use of one of the influenza vaccine products for children for the 2010-11 vaccination season. Is that true?

Yes, on August 5, ACIP recommended that Afluria, 0.5 mL, licensed for use in people age 36 months and older, not be used in children younger than age 9 years. Afluria is manufactured in Australia by CSL Laboratories for the U.S. market. CSL's 2010 Southern Hemisphere influenza vaccine (Fluvax and Fluvax Junior) has been associated with increased post-marketing reports of fever and febrile seizures in children predominantly younger than age 5 years as compared to previous years. ACIP further recommended that Afluria could be administered to children ages 5 through 8 years who are at high risk for influenza complications if there is no other age-appropriate TIV available, after risks and benefits of using this vaccine in this age group have been discussed with the parent or guardian. The vaccine should not be given to children younger than age 5 years. For detailed information, go to www.cdc.gov/media/pressrel/2010/s100806.htm.

What if a child is 8 years old on September 15, has an indication for 2 doses of 2010-11 flu vaccine, gets his first dose on September 15, and turns 9 years old on October 1? Does the child still need the 2<sup>nd</sup> dose of 2010-11 flu vaccine? Or (being 9 years old) will he/she not need the 2<sup>nd</sup> dose of 2010-11 flu vaccine this year?

No, a second dose is not necessary for children being vaccinated for the first time who were aged 8 years at the time of the first dose but who are seen again after they have reached age 9 years. (From: <a href="http://www.cdc.gov/flu/professionals/acip/specificpopulations.htm">http://www.cdc.gov/flu/professionals/acip/specificpopulations.htm</a>)

If a child receives influenza vaccine at age 34 or 35 months for the first time (0.25 mL dose) and then returns for the second dose at age 37 months, should we give another 0.25 mL dose or should we give the 0.5 mL dose that is indicated for ages 3 and older?

The child should always receive the dose appropriate for his or her age at the time of the clinic visit; at age 37 months that would be 0.5 mL.

### When a child needs 2 doses of influenza vaccine, can I give one dose of each type (injectable and nasal spray)?

Yes. As long as a child is eligible to receive nasal spray vaccine (i.e., is in the proper age range and health status), it is acceptable to give 1 dose of each type of influenza vaccine. The doses should be spaced at least 4 weeks apart.

### Vaccination of Persons Age ≥65 Years

# I have heard there's a new flu vaccine formulation for elderly patients. Are we required to use this formulation for these patients?

Fluzone High-Dose from Sanofi Pasteur is a newly approved inactivated trivalent vaccine containing 60 mcg of hemagglutinin antigen per influenza vaccine virus strain and is an alternative inactivated vaccine for persons aged 65 years and older. ACIP recommends that all persons aged ≥65 years receive an inactivated 2010--11 seasonal influenza vaccination but has not expressed a preference for Fluzone High-Dose or any other inactivated influenza vaccine for use in persons aged ≥65 years. Whether or not the higher postvaccination immune responses observed among Fluzone High-Dose vaccine recipients

<u>will result in greater protection against influenza illness is not known</u>. Persons aged younger than 65 years who receive inactivated influenza vaccine should be administered a standard-dose TIV preparation.

#### **Influenza Vaccination Issues for Health Care Workers**

#### Should health care providers receive flu vaccine?

YES! CDC and many medical professional organizations recommend all health care workers receive an annual influenza vaccine. Because healthcare personnel (HCP) provide care to patients at high risk for complications of influenza, HCP are considered a high-priority group for receiving vaccination. Achieving high rates of vaccination among HCP will protect staff and their patients, and reduce disease burden and healthcare costs. It is important to vaccinate ALL hospital and outpatient-care personnel, especially those that have direct contact with patients. In addition to physicians and nurses, vaccination in a hospital setting also includes full-time and part-time employees in radiology, laboratories, pharmacy, human resources, facilities management (housekeeping), food services, or laundry. Vaccinate volunteers as well. Others that should be vaccinated are emergency response workers, employees of nursing homes and assisted living programs, and providers of home care.

<u>Mandatory annual influenza vaccination of healthcare workers</u> is currently recommended by vaccination recommended by: the American Academy of Pediatrics; the American College of Physicians; the Association of Professionals in Infection; the Control; the Infectious Disease Society of America; the Society for Healthcare Epidemiology of America; and, the National Patient Safety Organization.

- The American Academy of Pediatrics (AAP) policy, "Recommendation for Mandatory Influenza Immunization of All Health Care Personnel," can be found at <a href="http://aap.org/advocacy/releases/sept-flu.htm">http://aap.org/advocacy/releases/sept-flu.htm</a>.
- The Society for Healthcare Epidemiology of America (SHEA) published a position paper on influenza vaccination of healthcare personnel that has been endorsed by the Infectious Disease Society of America. For more information, go to: www.journals.uchicago.edu/doi/pdf/10.1086/656558

### What personal protective equipment is recommended for health-care workers who are giving LAIV (FluMist®)?

Personal protective equipment (gloves and masks) is not needed.

### Can a health care worker administer vaccine if they have a contraindication that prevents them from receiving it?

Yes. Only a health care worker with severe immunosuppression should not administer intranasal vaccine, and those persons will not be at work because of their condition.

# Can healthcare providers caring for immunosuppressed compromised patients get LAIV (FluMist)?

TIV is recommended for vaccinating healthcare providers, household members, and others who have close contact with severely immunosuppressed persons (e.g., patients with

hematopoietic stem cell transplants) <u>during those periods in which the immunosuppressed person requires care in a protective environment</u> (typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes). To reduce the theoretic risk for vaccine virus transmission, it is recommended that HCP who receive LAIV should avoid providing care for severely immunosuppressed patients requiring a protected environment for 7 days after vaccination, and hospital visitors who have received LAIV should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.

Healthy nonpregnant persons aged 2–49 years, including HCP, who have close contact with persons with lesser degrees of immunosuppression (e.g., persons with chronic immunocompromising conditions such as HIV infection, corticosteroid or chemotherapeutic medication use, or who are cared for in other hospital areas such as neonatal intensive care units) can receive TIV or LAIV.

#### **General Contraindications and Precautions**

#### Who should not get a flu shot?

- People who have a severe allergy (anaphylaxis, urticaria, bronchospasm) to chicken eggs,
- People who have had a severe reaction to an influenza vaccination,
- People who have developed Guillian-Barré syndrome within 6 weeks of getting an influenza vaccine,
- Children less than 6 months of age (influenza vaccine is not approved for this age group), and
- People who have a moderate to severe illness with a fever (they should wait until they recover to get vaccinated).

Persons should talk with their doctor before getting a flu shot if they:

- 1. Have ever had a severe allergic reaction to eggs, latex, or to a previous flu shot or
- 2. Have a history of Guillain–Barré Syndrome that occurred after receiving influenza vaccine

If the person is sick with a fever when he goes to get his flu shot, the doctor or nurse may recommend getting the vaccine at a later date. However, a person can get a flu shot at the same time he has a respiratory illness without fever or if he has another mild illness.

#### More about egg allergy:

If the nature of an egg or latex allergy is unclear, consider consultation with an allergist. Protocols for desensitization have been published. For allergies other than severe, give the vaccine. If a person can eat eggs in any form, they may receive influenza vaccine without prior testing. The Food Allergy & Anaphylaxis Network is a good food allergy resource for health professionals, online at <a href="https://www.foodallergy.org/section/for-health-professionals1">www.foodallergy.org/section/for-health-professionals1</a>.

#### Can a person with a latex allergy safely receive flu vaccine?

Persons with latex allergies that are not anaphylactic may be vaccinated as usual. For example, vaccination is safe if the latex sensitivity is contact-type allergy (the most common type), such as with persons who have prolonged contact with latex-containing gloves.

Although rare, persons who have had a severe, anaphylactic reaction to latex should generally **not** be given vaccines that have been in contact with natural rubber, unless the benefit of vaccination outweighs the risk of a potential allergic reaction. The table "Latex in Vaccine Packaging" from the Centers for Disease Control and Prevention (CDC) "Pink Book" has been updated online (at

www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf) to include current information about which flu vaccine formulations contain latex.

**NOTE:** Secretary of Health Mary Selecky has temporarily suspended Washington's thimerosal law that limits the amount of mercury (thimerosal) in 2010-2011 influenza vaccine allowed for pregnant women and children younger than three years old. The suspension is effective October 07, 2010 through June 30, 2011 and applies only to seasonal influenza vaccine in multi-dose vials.

Latex-allergic pregnant women and children under 3 years of age may receive flu vaccine from single-dose vials or multi-dose vials while the emergency suspension is in place. Preservative-free flu vaccine is also available in *single-dose* <u>vials</u> that do not contain thimerosal or latex and can be used for these groups.

#### **LAIV** Issues

Who can be vaccinated with the nasal-spray flu vaccine LAIV (FluMist®)?

LAIV (FluMist®) is approved for use in healthy people 2-49 years of age who are not pregnant.

#### Who should not be vaccinated with the nasal-spray flu vaccine LAIV (FluMist®)?

- People less than 2 years of age
- People 50 years of age and over
- People with a medical condition that places them at high risk for complications from
  influenza, including those with chronic heart or lung disease, such as asthma or reactive
  airway disease; people with medical conditions such as diabetes or kidney failure; or
  people with illnesses that weaken the immune system, or who take medications that can
  weaken the immune system.
- Children <5 years old with a history of recurrent wheezing</li>
- Children or adolescents receiving aspirin
- People with a history of Guillain–Barré Syndrome that occurred after receiving influenza vaccine
- Pregnant women
- People who have a severe allergy to chicken eggs or who are allergic to any of the nasal spray vaccine components.

Are there any contraindications to giving breastfeeding mothers LAIV (FluMist®)?

Breastfeeding is not a contraindication for FluMist®. See

www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm for a list of contraindications for FluMist®

### Can the nasal-spray flu vaccine LAIV (FluMist®) be given to patients when they are ill?

The nasal-spray flu vaccine LAIV (FluMist®) can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered.

### Can people receiving the nasal-spray flu vaccine LAIV (FluMist®) pass the vaccine viruses to others?

In clinical studies, transmission of vaccine viruses to close contacts has occurred only rarely. The current estimated risk of getting infected with vaccine virus after close contact with a person vaccinated with the nasal-spray flu vaccine is low (0.6%-2.4%). Because the viruses are weakened, infection is unlikely to result in influenza illness symptoms because the vaccine viruses have not been shown to mutate into typical or naturally occurring influenza viruses.

### Can contacts of people with weakened immune systems get the nasal-spray flu vaccine LAIV (FluMist®)?

People who are in contact with others with severely weakened immune systems when they are being cared for in a protective environment (for example, people with hematopoietic stem cell transplants), should not get LAIV (FluMist®). People who have contact with others with lesser degrees of immunosuppression (for example, people with diabetes, people with asthma taking corticosteroids, or people infected with HIV) can get LAIV (FluMist®).

#### How is the nasal spray flu vaccine different than the injectable vaccine?

The first and obvious difference is in the way they're administered. A second important difference is that, unlike the flu shot, the nasal spray flu vaccine does contain live viruses. In the nasal spray flu vaccine, the viruses are attenuated (weakened) and **cannot cause flu illness**. The weakened viruses are cold-adapted, which means they are designed to only cause infection at the cooler temperatures found within the nose. The viruses cannot infect the lungs or other areas where warmer temperatures exist.

#### Does the nasal-spray flu vaccine LAIV (FluMist®) contain thimerosal?

No, the nasal-spray flu vaccine LAIV **(FluMist®)** does not contain thimerosal or any other preservative.

### For planned pregnancies, how long should a woman wait after receiving nasal spray flu vaccines before becoming pregnant?

There are no studies of live attenuated influenza vaccine among women who are pregnant or who are planning to become pregnant. However, the vaccine virus is cold-adapted and replicates in the nasopharyngeal tissues rather than at core body temperature. Consequently, infection of a fetus with live attenuated influenza virus is very unlikely. It is not necessary to defer pregnancy for a specific interval following receipt of live attenuated influenza vaccine.

### Can a woman who is breastfeeding receive live attenuated influenza vaccine (LAIV)?

Yes. Breastfeeding is not a contraindication for routine vaccination of the breastfeeding woman with any influenza vaccine, including LAIV.

### Can the nasal-spray flu vaccine LAIV (FluMist®) be used together with influenza antiviral medications?

If a person is taking an influenza antiviral drug (including Tamiflu® or Relenza®), then the nasal spray flu vaccine should not be given until 48 hours after the last dose of the influenza antiviral medication was given. If a person takes antiviral drugs within two weeks of getting the nasal spray flu vaccine, that person should get revaccinated. (The antiviral drugs will have killed the vaccine viruses that are supposed to cause the immune response against those viruses.) *Antiviral drugs can be taken with the inactivated (i.e. killed) flu vaccine*.

#### **Adverse Reactions from Flu Vaccine**

#### What are the possible adverse reactions from a flu shot?

Almost all people who get influenza vaccine have no serious problems from it. However, some people will have soreness, redness, or swelling where the shot was given, low grade fever, and/or aches after getting a flu shot. If these problems occur, they begin soon after the shot and usually last one to two days.

The risk of a flu shot causing serious harm, or death, is extremely small. However, a vaccine, like any medicine, may rarely cause serious problems, such as:

- Severe allergic reactions. Life-threatening allergic reactions are very rare. Signs of serious allergic reaction can include breathing problems, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat, or dizziness. If they do occur, it is within a few minutes to a few hours after the shot. These reactions are more likely to occur among persons with a severe allergy to eggs, because the viruses used in the influenza vaccine are grown in hens' eggs. People who have had a severe reaction to eggs or to a flu shot in the past should not get a flu shot before seeing a physician.
- Ocular and Respiratory Symptoms. Ocular or respiratory symptoms have been reported occasionally within 24 hours after TIV administration, but these symptoms typically are mild and resolve quickly without specific treatment.
  - Oculorespiratory syndrome (ORS), an acute, self-limited reaction to TIV with prominent ocular and respiratory symptoms, was first described during the 2000–01 influenza season in Canada. The initial case-definition for ORS was the onset of one or more of the following within 2–24 hours after receiving TIV: bilateral red eyes and/or facial edema and/or respiratory symptoms (coughing, wheezing, chest tightness, difficulty breathing, sore throat, hoarseness or difficulty swallowing, cough, wheeze, chest tightness, difficulty breathing, sore throat, or facial swelling). ORS was first described in Canada and strongly associated with one vaccine preparation (Fluviral S/F, Shire Biologics, Quebec, Canada) not available in the United States during the 2000–01 influenza season. Subsequent investigations identified persons with ocular or respiratory symptoms meeting an ORS case-definition in safety monitoring systems and trials that had been conducted before 2000 in Canada, the United States, and several European countries.
- **Febrile seizures**. Administration of CSL's 2010 Southern Hemisphere influenza vaccine Fluvax has been associated with increased postmarketing reports of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years. CSL has changed its package insert for its influenza vaccine licensed in the United States under the name Afluria to include this warning. Although the manufacturer will not be supplying the 0.25 mL presentation to the United States that is used in

children 6 months - 35 months of age, the 0.5 mL single dose, prefilled syringe and 5 mL multi-dose vial presentation will be distributed.

The *ACIP recommends that Afluria should not be used in children aged 6 months through 8 years*. Other age-appropriate, licensed seasonal influenza vaccine formulations should be used for prevention of influenza in children aged 6 months through 8 years. If no other age-appropriate, licensed seasonal influenza vaccine is available for a child aged 5 years through 8 years old who has a medical condition that increases their risk for influenza complications, Afluria may be given, and providers should discuss the benefits and risks of influenza vaccination with the parents or caregivers before administering Afluria.

Guillain-Barré syndrome (GBS). The annual incidence of GBS is 10–20 cases per 1 million adults. Substantial evidence exists that multiple infectious illnesses, most notably Campylobacter jejuni gastrointestinal infections and upper respiratory tract infections, are associated with GBS. A recent study identified serologically confirmed influenza virus infection as a trigger of GBS, with time from onset of influenza illness to GBS of 3–30 days. The estimated frequency of influenza-related GBS was four to seven times higher than the frequency that has been estimated for influenza-vaccine–associated GBS.

The 1976 swine influenza vaccine was associated with an increased frequency of GBS, estimated at one additional case of GBS per 100,000 persons vaccinated. The risk for influenza-vaccine—associated GBS was higher among persons aged 25 years and older than among persons aged younger than 25 years. However, obtaining epidemiologic evidence for a small increase in risk for a rare condition with multiple causes is difficult, and no evidence consistently exists for a causal relation between subsequent vaccines prepared from other influenza viruses and GBS.

For more information about adverse reactions following the inactivated influenza vaccine, including recommendations for flu vaccination in subsequent seasons, see <a href="https://www.cdc.gov/flu/professionals/acip/adverseTIV.htm">www.cdc.gov/flu/professionals/acip/adverseTIV.htm</a>

# What side effects are associated with the nasal-spray flu vaccine LAIV (FluMist®)?

- Most common adverse reactions are runny nose or nasal congestion in all ages, fever
   >100F in children 2-6 years of age, and sore throat in adults.
- Adults also reported headache, sore throat, tiredness/weakness, muscles aches, cough, chills, and sinusitis more often after LAIV than after an intranasal placebo.
- In a placebo-controlled safety study conducted in a large Health Maintenance Organization (HMO) in children 1-17 years of age (n = 9689), an increase in <u>asthma</u> events, captured by review of diagnostic codes, was observed in children <5 years of age (Relative Risk 3.53, 90% CI: 1.1, 15.7). One study of 8352 children aged 6 through 59 months showed that the younger children aged 6 through 23 months had increased rates of wheezing in the 42 days after LAIV (6%) than TIV (4%) (LAIV is not licensed for this age group). Children aged 24 through 59 months had similar rates of wheezing after LAIV (2%) and TIV (3%).
- In children aged 2 through 6 years, <u>fever >100° F</u> occurred more often after first dose LAIV (16%) than placebo (11%). Adults receiving LAIV did not have an increased risk for fever after vaccination compared with placebo.

For more information about adverse reactions following LAIV, see www.cdc.gov/flu/professionals/acip/adverseLAIV.htm.

### **Administering Influenza Vaccine**

### Some injectable influenza vaccine comes with a 5/8" needle attached. I thought we were supposed to use a 1-1 1/2" needle for this IM vaccine in adults.

You're right. For intramuscular injection ACIP generally recommends the use of at least a 1" needle in adults. Some experts feel that a shorter needle can be used in adults weighing less than 60 kg, but ONLY if administration is in the deltoid and ONLY if the skin is stretched tight and the needle is placed at a 90 degree angle to the skin.

### We mistakenly gave a 0.25mL (pediatric) dose rather than the recommended 0.5mL dose to a 3-year-old child. Should the first dose be repeated?

Yes. Any vaccination using less than the standard dose should not be counted, and the person should be re-vaccinated according to age. However, if the patient is still in the office or can return the same clinic day, another 0.25 ml dose can be given to complete the 0.5 ml dose. Otherwise, the correct 0.5 ml dose can be given as soon as the next day.

# If adult inactivated influenza vaccine is not available, can a *high-risk* adult or a *high-risk* child receive the pediatric product (thimerosal preservative-free 0.25 ml dose) as long as they are given 0.5ml?

When an adequate supply of adult formulation is available in the community, as is the case this season, CDC does not recommend that providers combine two 0.25mL doses of pediatric influenza vaccine to vaccinate a single individual who requires a 0.5mL dose of vaccine.

### Should I repeat a dose of influenza vaccine administered by an incorrect route (such as intradermal or subcutaneous)?

No. If the DOSE (amount) of vaccine was age-appropriate, it can be counted as valid regardless of the ROUTE by which it was given.

### **Storage and Handling of Influenza Vaccine**

#### At what temperature should flu vaccine be stored?

Both the injectable vaccine and the nasal-spray flu vaccine must be stored in a refrigerator at 2-8°C (35-46°F).

### Can I pre-fill syringes for a flu shot clinic? If so, how long before the clinic can I pre-fill the syringes?

CDC does not recommend pre-filling syringes because of the potential for administration errors. The same person who draws vaccine should ideally be the person who administers it. Once the needle is placed on the syringe it should be used immediately. Any syringes except those filled by the manufacturer should be discarded at the end of the clinic day.